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United States Patent & Trademark Office
Rule 132 Affidavit

Appl. No.	:	10/800,608
Applicant	:	Stephen Truesdale Carney
Filed	:	March 15, 2004
TC/A.U.	:	1655
Examiner	:	Patricia A. Leith

Second Affidavit of Lawrence D. Rink

I, Lawrence D. Rink, M.D., F.A.C.C., hereby duly depose and say as follows:

1. I am a Fellow of the American College of Cardiology and have been certified member of the American Board of Internal Medicine, Cardiovascular Disease, since 1983.

2. I have lectured, performed clinical studies and published numerous articles on the issues of cardiovascular disease and hyperlipidemia.

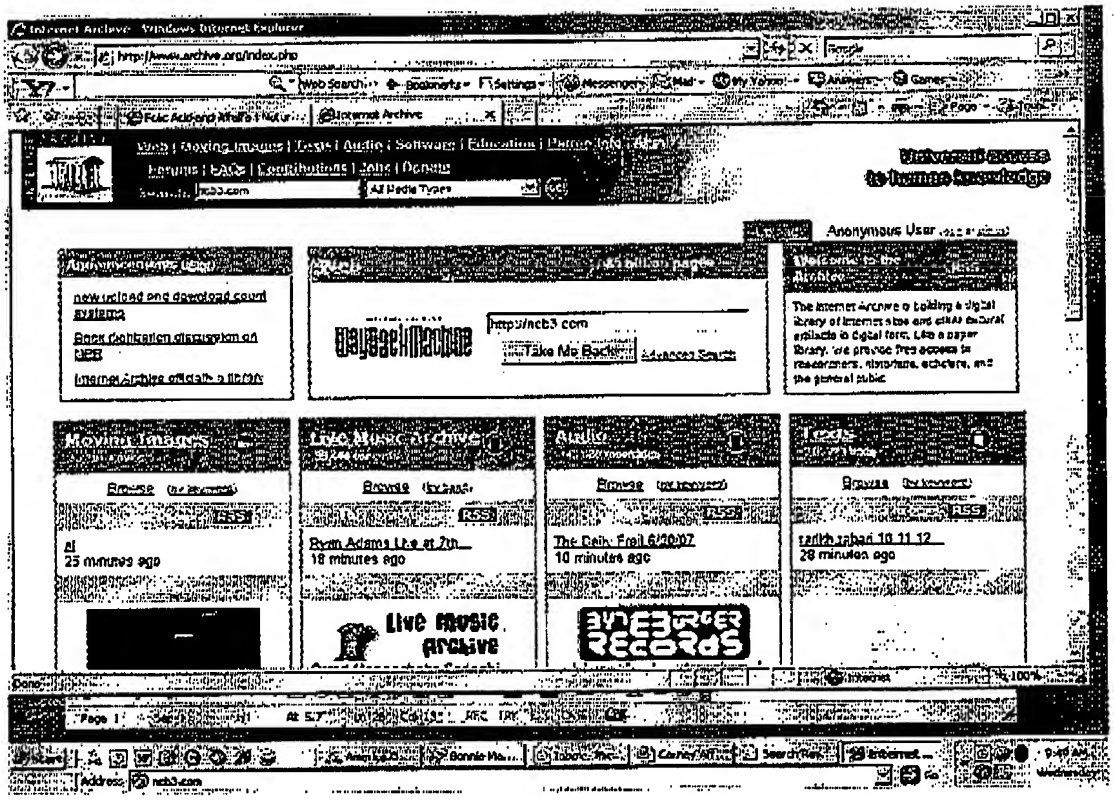
3. Upon the request of Mr. Stephen T. Carney and as a work for hire pursuant to a valid Non Disclosure and Confidentiality Agreement, I conducted the Folic Acid and Alfalfa, The FALL Study, (the "Study") described and made part of the above referenced Patent Application.

4. While I am the author of the Study, the Study was completed as a work for hire and on behalf of the Applicant, Stephen T. Carney. As of the date of this Affidavit, I have never caused said Study to be published or decimated to the public.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed.

Signed under the pains and penalties of perjury this _____ day of _____ _____, 2007

_____
Lawrence D Rink, M.D. FACC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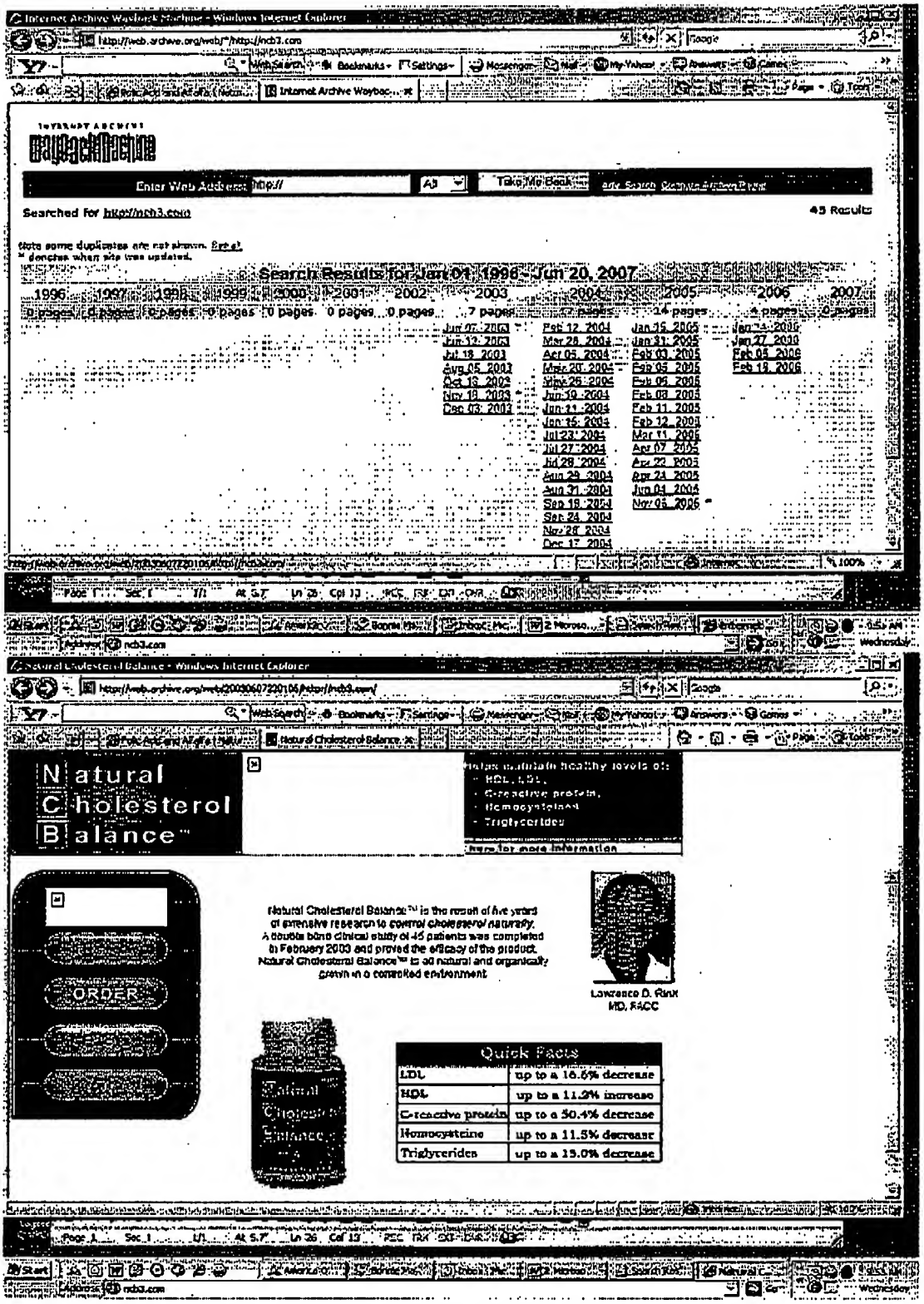
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Natural Cholesterol Balance™
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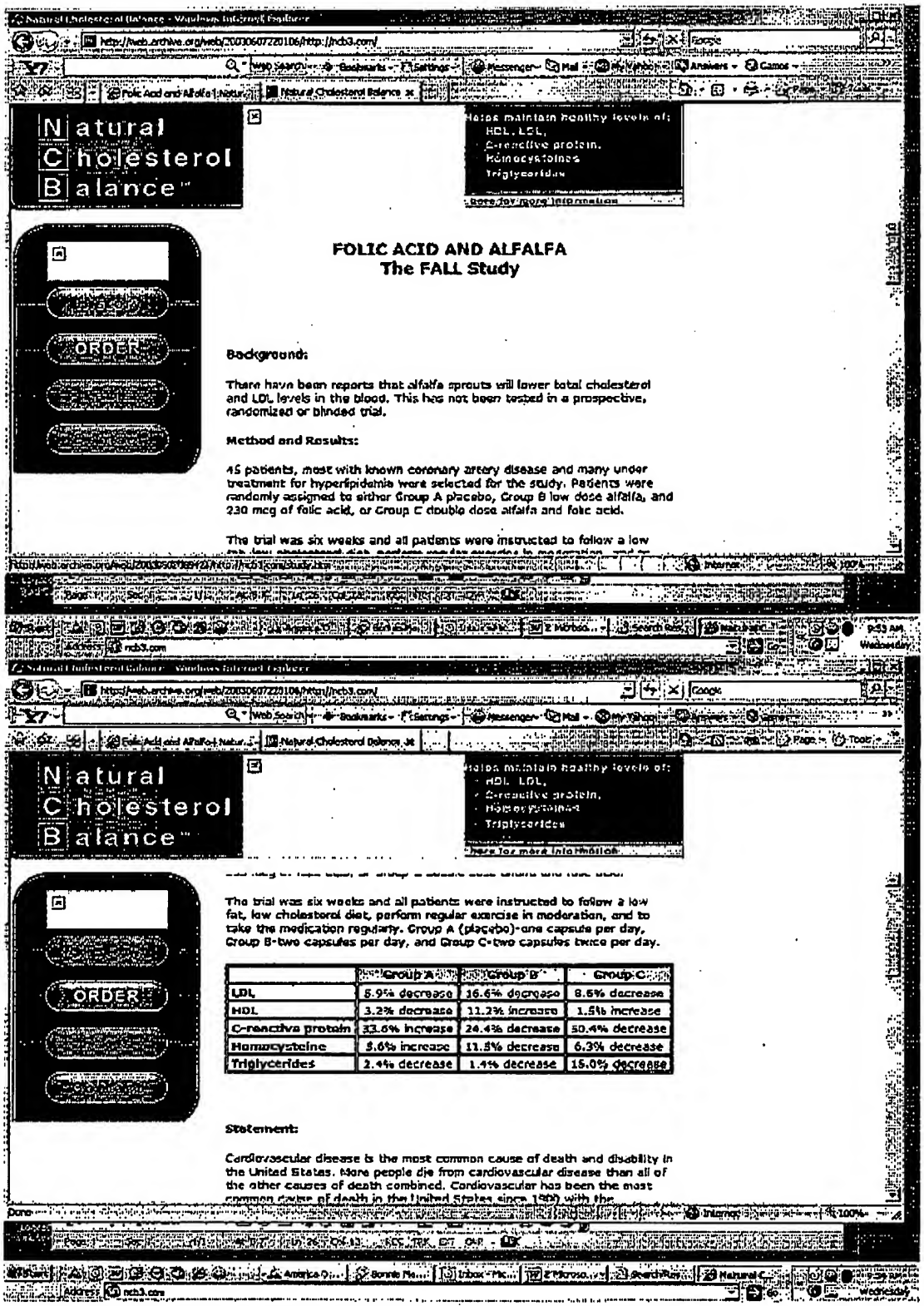
Natural Cholesterol Balance™ is the result of five years of extensive research to control cholesterol naturally. A double blind clinical study of 45 patients was completed in February 2003 and proved the efficacy of the product. Natural Cholesterol Balance™ is all natural and organically grown in a controlled environment
Lawrence D. Rinx MD, FACC
Quick Facts
LDL up to a 16.6% decrease
HDL up to a 11.2% increase
C-reactive protein up to a 50.4% decrease
Homocysteine up to a 11.5% decrease
Triglycerides up to a 15.0% decrease


Natural Cholesterol Balance™
Helps maintain healthy levels of:
HDL, LDL,
C-reactive protein,
Homocysteine
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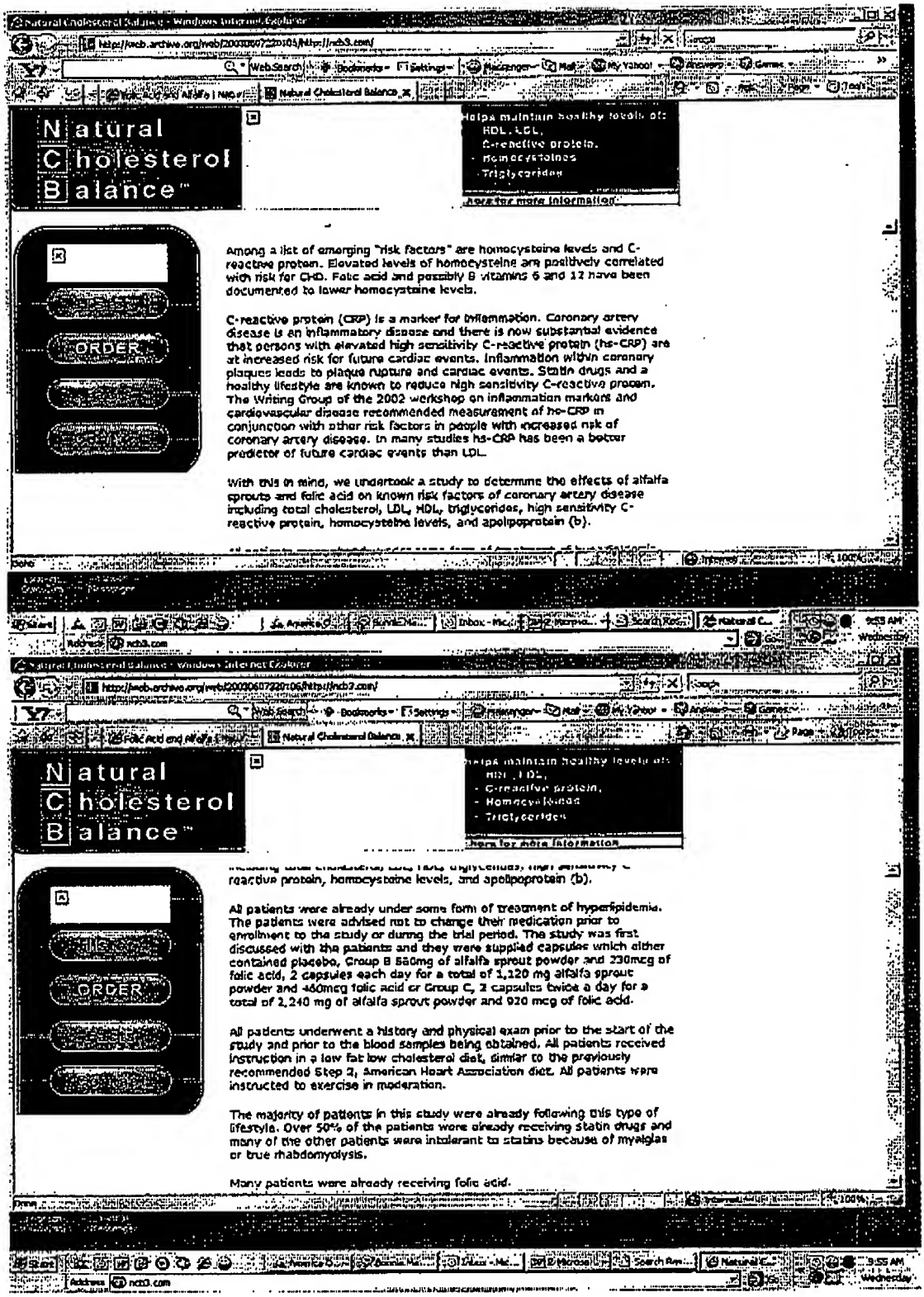
FOLIC ACID AND ALFALFA
The FALL Study
Background:
There have been reports that alfalfa sprouts will lower total cholesterol and LDL levels in the blood. This has not been tested in a prospective, randomized or blinded trial.
Method and Results:
45 patients, most with known coronary artery disease and many under treatment for hyperlipidemia were selected for the study. Patients were randomly assigned to either Group A placebo, Group B low dose alfalfa, and 230 mcg of folic acid, or Group C double dose alfalfa and folic acid.
The trial was six weeks and all patients were instructed to follow a low fat, low cholesterol diet, perform regular exercise in moderation, and to take the medication regularly. Group A (placebo)-one capsule per day, Group B-two capsules per day, and Group C-two capsules twice per day.
Group A
Group B
Group C
LDL
5.9% decrease
16.6% decrease
8.6% decrease
HDL
3.2% decrease
11.2% increase
1.5% increase
C-reactive protein
33.6% increase
24.4% decrease
50.4% decrease
Homocysteine
5.6% increase
11.5% decrease
6.3% decrease
Triglycerides
2.4% decrease
1.4% decrease
15.0% decrease
Statement:
Cardiovascular disease is the most common cause of death and disability in the United States. More people die from cardiovascular disease than all of the other causes of death combined. Cardiovascular has been the most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Among a list of emerging "risk factors" are homocysteine levels and C-reactive protein. Elevated levels of homocysteine are positively correlated with risk for CHD. Folic acid and possibly B vitamins 6 and 12 have been documented to lower homocysteine levels.
C-reactive protein (CRP) is a marker for inflammation. Coronary artery disease is an inflammatory disease and there is now substantial evidence that persons with elevated high sensitivity C-reactive protein (hs-CRP) are at increased risk for future cardiac events. Inflammation within coronary plaques leads to plaque rupture and cardiac events. Statin drugs and a healthy lifestyle are known to reduce high sensitivity C-reactive protein. The Writing Group of the 2002 workshop on inflammation markers and cardiovascular disease recommended measurement of hs-CRP in conjunction with other risk factors in people with increased risk of coronary artery disease. In many studies hs-CRP has been a better predictor of future cardiac events than LDL.
With this in mind, we undertook a study to determine the effects of alfalfa sprouts and folic acid on known risk factors of coronary artery disease including total cholesterol, LDL, HDL, triglycerides, high sensitivity C-reactive protein, homocysteine levels, and apolipoprotein (b).
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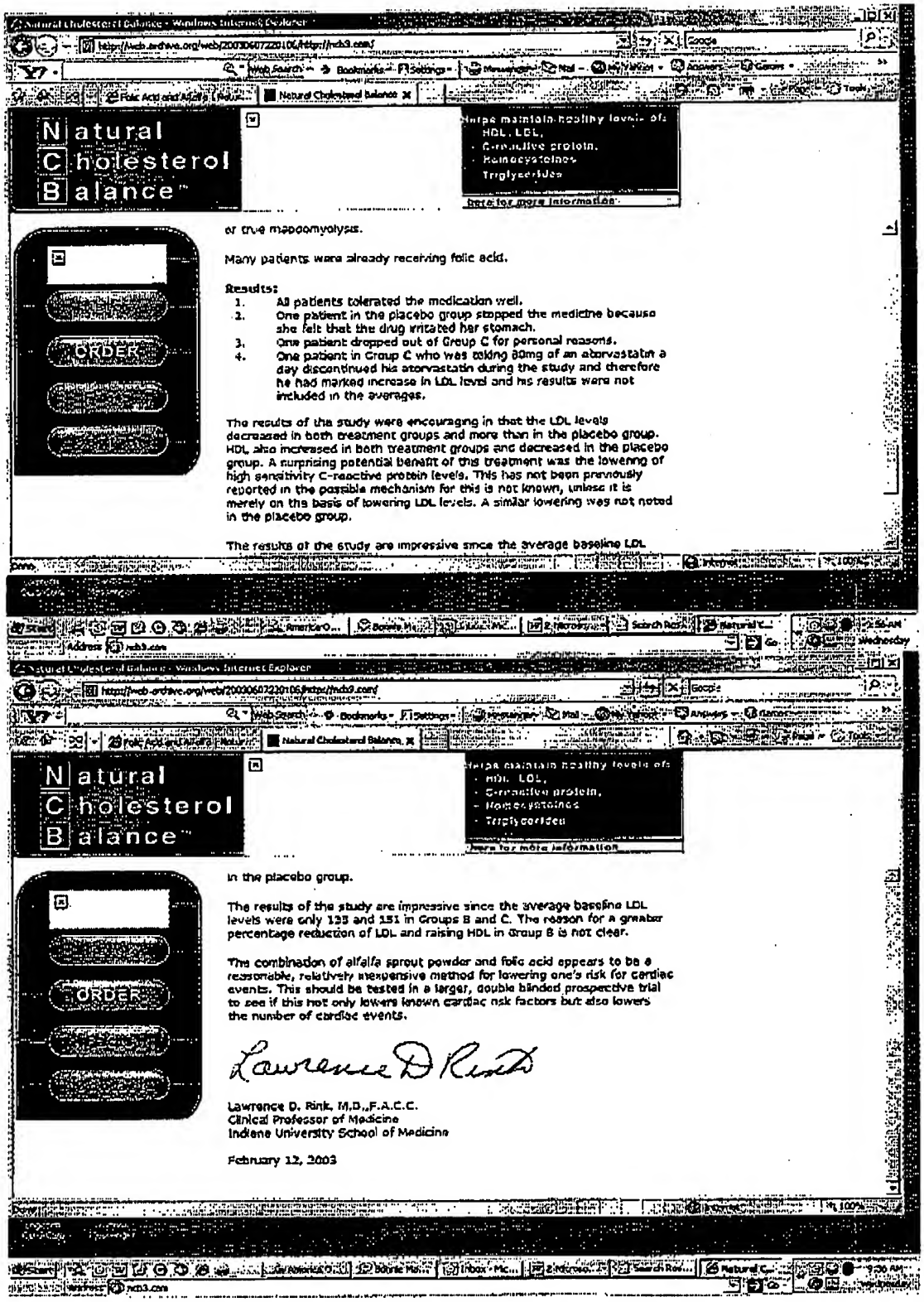
All patients were already under some form of treatment of hyperlipidemia. The patients were advised not to change their medication prior to enrollment to the study or during the trial period. The study was first discussed with the patients and they were supplied capsules which either contained placebo, Group B 560mg of alfalfa sprout powder and 230mcg of folic acid, 2 capsules each day for a total of 1,120 mg alfalfa sprout powder and 460mcg folic acid or Group C, 2 capsules twice a day for a total of 2,240 mg of alfalfa sprout powder and 920 mcg of folic acid.
All patients underwent a history and physical exam prior to the start of the study and prior to the blood samples being obtained. All patients received instruction in a low fat low cholesterol diet, similar to the previously recommended Step 2, American Heart Association diet. All patients were instructed to exercise in moderation.
The majority of patients in this study were already following this type of lifestyle. Over 50% of the patients were already receiving statin drugs and many of the other patients were intolerant to statins because of myalgias or true rhabdomyolysis.
Many patients were already receiving folic acid.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or true rhabdomyolysis.
Many patients were already receiving folic acid.
Results:
1. All patients tolerated the medication well.
2. One patient in the placebo group stopped the medicine because she felt that the drug irritated her stomach.
3. One patient dropped out of Group C for personal reasons.
4. One patient in Group C who was taking 80mg of an atorvastatin a day discontinued his atorvastatin during the study and therefore he had marked increase in LDL level and his results were not included in the averages.
The results of the study were encouraging in that the LDL levels decreased in both treatment groups and more than in the placebo group. HDL also increased in both treatment groups and decreased in the placebo group. A surprising potential benefit of this treatment was the lowering of high sensitivity C-reactive protein levels. This has not been previously reported in the possible mechanism for this is not known, unless it is merely on the basis of lowering LDL levels. A similar lowering was not noted in the placebo group.
The results of the study are impressive since the average baseline LDL
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in the placebo group.
The results of the study are impressive since the average baseline LDL levels were only 133 and 151 in Groups B and C. The reason for a greater percentage reduction of LDL and raising HDL in Group B is not clear.
The combination of alfalfa sprout powder and folic acid appears to be a reasonable, relatively inexpensive method for lowering one's risk for cardiac events. This should be tested in a larger, double blinded prospective trial to see if this not only lowers known cardiac risk factors but also lowers the number of cardiac events.
Lawrence D. Rink, M.D., F.A.C.C.
Clinical Professor of Medicine
Indiana University School of Medicine
February 12, 2003